North Texas Regional IRB – IRB Submission Quick Reference "Cheat Sheet"

This document is intended to be a quick-reference guide for researchers who are new to submitting studies to the NTR IRB. ***The NTR IRB website has lots of additional guidance – visit https://www.unthsc.edu/north-texas-regional-irb/ !***

1. If you do not already have an IRBNet user account, please visit http://www.irbnet.org and click the "New User Registration" link to create your IRBNet account. The website will walk you through the process – be sure to check the email addresses you used to register in order to confirm and verify your IRBNet account.

2. Once your IRBNet user account has been created, log into the IRBNet website with your credentials. Click the link on the left-hand sidebar to "Create New Project." Enter the project title and the Principal Investigator's name. All the other fields are optional.

   On the next screen, it is suggested to start with Step 2 by clicking the "Start a Wizard" button at the bottom, then click the small link that says "North Texas Regional IRB – New Protocol Application Form." Click next, and the Wizard will guide you through a series of dynamic questions about your project. Answer all the questions, clicking "Next" to proceed to the next screen. Once all the questions in the Wizard have been answered, you will reach a Principal Investigator Attestation page. Sign and complete the attestation. The final "Complete" page will provide a list of suggested Forms & Templates that *may* apply to your project. Click "Save & Exit," and you will be taken to your project's Designer page.

3. The Designer page in IRBNet is where you will upload all the required documents for your project, including completed forms and templates. To access blank, fillable Forms & Templates, visit the NTR IRB Forms page.

4. Researchers are required to submit a completed Protocol Synopsis with every new project. The NTR IRB currently offers two versions of the Protocol Synopsis template: the Chart Review Protocol Synopsis Template, which is used only for medical chart review studies; and the "Protocol Synopsis Template (General)," which must be used for all other types of projects. Download the version that applies to your project. **Note**: *A guidance document has been specifically prepared to assist you in completing the general Protocol Synopsis Template - the "Master Protocol Synopsis Guidance Sheet."*

5. In addition to the Protocol Synopsis document, you will need to download any other Forms or Templates that apply to your project. Examples include Informed Consent templates; HIPAA Authorization Forms; requests for Waivers of HIPAA or the Informed Consent process; and more. Once you have downloaded all the required Forms and Templates to your computer, complete them with information that is applicable to your project. You will also need to create any other research-related materials that you intend to use in your project, like recruitment flyers or email scripts, surveys or questionnaires, data collection sheets, and so on.

6. Once all your needed Forms, Templates, and associated study documents are completed and ready to be uploaded, visit the Designer page in IRBNet, and upload all the necessary documents to your project.

7. In addition to your study specific documents, be sure to upload all required trainings (including evidence of training in human subject research, such as CITI, for all key personnel), licenses, the CV of the PI, etc. For studies that will be reviewed at the Expedited or Full Board level, the IRB also requires signed Conflict of Interest forms for all key personnel. Please upload one file for each different type of training; for instance, one file containing all Human Subject Protection Training for all key personnel, one file containing Conflict of Interest forms for all study personnel, etc.

   If you will be working with any external collaborators who are not affiliated with UNT Dallas, UNTHSC, or JPS, please upload a transcript of the training modules that were completed so that the IRB can review the modules

and determine whether the modules are equivalent to the modules that are required by the NTR IRB.

8. Before submitting the project for IRB review, remember to share the project with key members of the study team and the appropriate personnel from your home institution. There are three levels of user access to projects in IRBNet: Full access, write access, and read only access. Choose the appropriate level of access depending upon the role of the individual personnel in your project.

9. The Principal Investigator is required to sign all projects in IRBNet prior to study submission. On the left-hand sidebar, click "Sign this package" to begin the signature process. *Please note that the IRB is not able to accept the signature of study personnel in place of the Principal Investigator.*

10. When the project is complete and ready to be submitted to the IRB, click "Submit this package" on the left-hand sidebar and follow the instructions to submit the package for IRB review.

11. After you have submitted your project in IRBNet, the IRB will conduct a preliminary completeness check of your submission within a few business days and will provide feedback about missing or incomplete documents.

12. Once you have uploaded all of the required documents and answered the IRB's questions from the completeness check (if any), you must click the link to "Mark Revisions Complete". **PLEASE NOTE that the IRB will not be informed that the project is ready without completing this important step.**

13. Once the IRB has received your updated project, the IRB will complete a more thorough review of your study documents. Please note that it is likely that the IRB will send detailed requests for revisions and clarifications. If this is the case, the IRB will unlock the package in IRBNet to let you know that your response is needed before continuing with the review of the project. IRBNet will send an email to notify you that the IRB has unlocked the package pending your response.

14. After reviewing the Board's feedback, be sure to edit your study materials to address all of the IRB's comments and questions. When your revisions are completed, log into IRBNet and go to "My Projects," click on the appropriate project, and go to the Designer page. From the Designer page, you can delete study documents, upload new study documents, or use the pencil icon to upload a new version of a previously uploaded document. For each document that has been updated, be sure to upload two versions: one with tracked changes (if the document allows tracked changes), as well as a clean version to be stamped upon approval.

15. Be sure to create a separate memo which explains how each of the IRB's requests was addressed, and have the memo signed by the Principal Investigator prior to submission in IRBNet.

16. Again (the same as when you're responding to intake findings), once all of your revised study materials have been uploaded in IRBNet, you must click the link to "Mark Revisions Complete". When you complete this step, the package will automatically be re-locked in IRBNet and the IRB will be notified that your project is ready for additional review. **The IRB will review your resubmission, and if the IRB has no further questions and all items were addressed sufficiently, you will receive emails from IRBNet noting that the Board has approved your study. Hooray!**

Note: *The IRB may also request additional revisions and clarifications after reviewing your responses to the IRB's feedback. For this reason, please submit your study* ***EARLY*** *to accommodate the full IRB review process.*

Please contact the North Texas Regional IRB at NorthTexRegIRB@unthsc.edu with any additional questions about the IRB submission process.